DePuy Mitek Inc. a Johnson & Johnson company — never stop moving

K122425

NOV 5 2012

510(k) SUMMARY

Date Prepared	August 8, 2012
Submitter's Name and Address:	DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767
Contact Person	Yayoi Fujimaki Senior Regulatory Affairs Associate DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3541 Facsimile: 508-977-6911 e-mail: yfujima1@its.jnj.com
Name of Medical Device	Classification Name: Electrosurgical cutting and coagulation device and accessories: 21 CFR 878.4400 Common/Usual Name: Electrosurgical cutting and coagulation device and accessories: Arthroscope Proprietary Name: VAPR P50 Electrode VAPR S50 Electrode VAPR S90 Electrode VAPR P50 Electrode with Handcontrols VAPR S90 Electrode with Handcontrols FDA Classification: II FDA product code: GEI
Device Description	The VAPR system is electrosurgical system that utilizes bipolar technology specifically designed to provide a range of arthroscopic surgical treatments including soft tissue ablation, cutting and coagulation and temperature control. The VAPR system includes a generator, electrodes which facilitate access and control the delivery of energy to the joint space, and accessories such as a footswitch and electrodes.
Description of Change	This premarket notification is submitted to add HIP arthroscopy to the indication for use for the VAPR Electrodes listed in this section.

As a result, the Instructions for Use (IFU) will be updated to add the hip indication.

Besides the HIP indication addition, electrode shaft design (S50, P50 and P50 w/Hndcontrols) has been changed to the same single-shaft design of the predicates.

No other changes have been made to the devices covered by this submission.

Indications for Use

VAPR Suction Electrodes (P50, S50, S90, P50 w/Handcontrols and S90 w/Handcontrols)
The DePuy Mitek VAPR Electrodes for use with the VAPR System are intended for resection, ablation, excision of soft tissues, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

Substantial Equivalence

With the addition of the Hip indication, the VAPR Systems and electrodes which are the subject of this submission will have the same indication as the following electrodes currently on the market:

Product		510K Number
Electrode	VAPR LDS Electrode	K113545
	VAPR LPS Electrode	
	VAPR P90 Electrode	
	VAPR CP90 Electrode	
	VAPR CP90 Electrode w/Handcontrols	
Associated Generator	VAPR VUE Radiofrequency System	
	VAPR II Electrosurgical System	
	VAPR 3 Electrosurgical System	

Safety and Performance

Verification and Validation of the VAPR Electrodes included performance testing to demonstrate that the device is appropriate for hip arthroscopy. A summary of testing is provided in Table 1.

Table 1

Testing	Results
Device Insertion	Pass: No visible cracks or missing portions at the distal tip of the electrodes.
Shaft Bending	Pass: No visible splitting of heatshrink after one cycle of bending and straightening of the electrode handle and shaft.
Active Tip Engagement	Pass: The electrodes withstood with no breakage at the active tip.

Clinical Testing	No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The VAPR System and Electrodes, when used for hip arthroscopic surgeries, do not differ from the predicate devices in fundamental scientific technology.
Conclusion	Results of safety and performance and testing have demonstrated that the modified device is suitable for its intended use. Based on the indications for use and fundamental scientific technology, the VAPR Electrodes when used the VAPR system are shown to be appropriate for arthroscopy of the hip as well as substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DePuy Mitek, Incorporated
a Johnson and Johnson Company
% Yayoi Fujimaki
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

November 5, 2012

Re: K122425
Trade/Device Name: VAPR® P50 Electrode, VAPR® S50 Electrode, VAPR® S90 Electrode, VAPR® P50 Electrode with Handcontrols, VAPR® S90 Electrode with Handcontrols
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 8, 2012
Received: August 9, 2012

Dear Yayoi Fujimaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122425

Device Name: **VAPR® P50 Electrode, VAPR® S50 Electrode, VAPR® S90 Electrode, VAPR® P50 Electrode with Handcontrols, VAPR® S90 Electrode with Handcontrols**

Indications for Use:

The DePuy Mitek VAPR Electrodes for use with the VAPR System are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscpic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122425